

**REMARKS**

Review and reconsideration of the Office Action of September 26, 2005, is respectfully requested in view of the above amendments and the following remarks.

Applicant has amended Claims 1, 3, 4 and 7 to overcome the Examiner's rejection. Care has been taken to ensure that no new matter is added to the claims. Support for the amendment to Claim 1, is found in original Claims 8, 10, and 11, which are incorporated into Claim 1, and the Specification. Support for the amendments to Claims 3, 4 and 7 are found in the Specification.

**Present Invention**

The present invention is a process for the determination of parameters of a breath condensate by use of one or more sensors for measurement of the parameters, the measurement is carried out within a closed cassette in which the at least one sensor is located and solutions are dispensed from storage containers of the cassette and/or placed onto the sensor or sensors by influence on the storage containers from outside the cassette.

Specifically, the process of the present invention is a ready-to-use cassette which includes all of the required reactants, calibrants and other solutions for analyzing the breath condensate; and the cassette is self-contained before and after use.

**Office Action**

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

**Paragraph 1: Election/Restriction**

The Examiner acknowledged the election of Group I, Claims 1-11 with traverse.

Further, Applicant cancels Claims 11-24.

**Paragraphs 2-3: Rejection under 35 U.S.C. §112**

The Examiner rejected Claims 3-6 under 35 U.S.C. 112, first paragraph, as being indefinite. We considered the Examiner's comments on pages 2 and 3 of the Office Action.

Applicant considered Examiners rejection with regard to Claim 3 and traverses this rejection.

In response, Applicant amended Claim 3. Additionally, the Examiner is directed to the Specification at to the discussion in paragraphs [00012], [00019], [00022], [00025], and [00027]. Applicant states that in paragraph [00019] it is stated that the storage units are emptied by means 7 which acts on them from the outside. In paragraphs [00022], [00025], and [00027] refer to means 7 acting on the cassette walls from the outside. The Examiner is directed to the fact that the action of means 7 will cause the mixing of the contents of the different storage containers. Further, the Examiner is directed to paragraph [00012] where there is a discussion of the different ways the solution in the cassettes can be dispensed, which causes the mixing of the solutions in each cassette. It is also mentioned that this action is carried out by any apparatus that would allow the end results to be achieved, **breaking the walls of the storage containers within the cassette.**

Furthermore, with regard to the indefiniteness of Claim 6, that Claim has been canceled.

Withdrawal of the rejection is respectfully requested.

**Paragraphs 4-5: Rejection under 35 U.S.C. §112**

The Examiner rejected Claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant reviewed the Examiner's comments on page 3 of the Office Action.

In response, Applicant amended Claim 1 by narrowing the scope of the claim. Further, the errors in line 6 and line 9 of Claim 1 have been corrected. Claims 6, 10 and 11 are cancelled. Lastly, Claims 2 - 5, 7 and 9 are now dependant on an allowable base Claim 1.

Withdrawal of the rejection is requested.

**Paragraphs 6-7: Rejection under 35 USC § 102**

The Examiner rejects Claims 1, 2, 7, 8, 10, and 11 under 35 U.S.C. 102(b) as being anticipated by Gaston, IV, et al. (US 6,033,368).

Applicant cancels Claims 8, 10, and 11.

Applicant traverses the rejection to Claims 1, 2 and 7.

Applicant reviewed Gaston, IV, et al. (US 6,033,368) and noted that it discloses a condensate colorimetric nitrogen oxide analyzer which consists of two parts, one in which the condensate is collected and another one in which the measurement is carried out. Because of this Gaston, IV has a fundamental disadvantage, being that it is not designed for disposal. Before reuse of the device of Gaston, IV, the measuring device must be cleaned by removing the reactant condensate and disposing it in autoclavable containers to avoid infections of other patients or clinical staff.

Further, Gaston, IV does not disclose a process in which all reactants required for measurement of other than the sample breath condensate, are included in a self-contained cassette so that no reactants need to be added for measurement once the sample is introduced into the cassette. Nor does it disclose release or mixing of any reaction or calibration solutions within a self-contained cassette solely by action from outside the cassette.

In response, Applicant states that Claim 1 as amended is not anticipated by Gaston, IV, et al. (US 6,033,368). Applicant's invention as set out in Claim 1 involves more steps than merely the simple dilution of a breath condensate as described in Gaston, IV. Further, the process of the invention has two major advantages over the process and apparatus disclosed in Gaston, IV. First, a ready-to-use cassette is employed which includes all of the required reactants, calibrants and other solutions required for analyzing the breath condensate so that only a breath condensate sample needs to be added to the cassette for analysis of the sample. Secondly, the cassette is self-contained before and after use and is disposed without any leakage of any of the reactants and sample solutions in the cassette.

For the reasons set out above, withdrawal of the rejection is respectfully requested.

Paragraphs 8-12: Rejection under 35 USC § 103

The Examiner rejected claims 3-5 and 9 under 35 U.S.C. 103(a) as being unpatentable over Gaston, IV et al in view of Besemer, et al. Further, the Examiner rejected Claim 6 under 35 U.S.C. 103(a) as being unpatentable over Gaston, IV et al in

view of Besemer, et al. as applied to Claim 5., and further in view of Silkoff, et al.

Applicant states that Claim 6 is cancelled with this amendment.

Applicant traverses the rejection.

Applicant directs the Examiner to Applicant's comments above with regard to Gaston, IV, et al. (US 6,033,368). Further, the two advantages of Applicant's invention set out above are not taught by the prior art references cited by the Examiner. Further, the two advantages allow Applicant's process to be used in clinical examinations in hospitals and at home by a patient without assistance from medical personal.

The two advantages set out by Applicant's process are not taught or mentioned by the prior art references. The Examiner is reminded that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In this instance all of the limitations of Claim 1 are not taught by the references.

Further, Claims 3-5 and 9 are dependant upon Claim 1, and we have argued that Claim 1 is nonobvious. Therefore, since Claim 1 is an independent claim that is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). We conclude that Claims 3-5 and 9 are allowable because they depend upon an allowable Claim 1.

Accordingly, withdrawal of the rejection is respectfully requested.

All claims are now in condition for allowance. Favorable